

EC Declaration of Conformity

Manufacturer:

whose single Authorized EU-Representative:

We, the manufacturer, herewith declare that the products:

Disposable Medical face mask

Earloop 3ply

meet the provisions of Medical Directive 93/42/EEC which apply to them.

The medical device has been assigned to class I according to Annex IX of the Directive 93/42/EEC. It bears the mark



following the conformity assessment procedures relating to the EC Declaration of Conformity set out in Annex VII of Directive 93/42/EEC.

This Declaration of Conformity covers all medical devices as specified in the product list belonging to this declaration.

The product identified above complies with the essential requirements of the above EC Directives by meeting the following standards:

*EN 14683: 2019+AC: 2019; EN ISO 14971:2012; EN ISO 10993-1:2018;
EN ISO 10993-5:2009; EN ISO 10993-10:2013; EN 62366-1:2015;
EN ISO 15223-1:2016; EN 1041:2008+A1:2013*

The above mentioned declaration of conformity is exclusively under the responsibility of

Nam Tong. 25.10.2019

Place, date

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